

### Remarks

Applicants acknowledge receipt of the Office Action mailed December 27, 2008.

Applicants respectfully request reconsideration and withdrawal of the rejections and objections in view of the foregoing amendments and the following remarks. Claims 1-5, 12, 14-19, and 26 are under consideration. New claim 28, which depends from claim 5 and incorporates the limitations of claim 14, has been added, and is supported by those original claims. Claims 6-11, 13, 20-25 and 27 are pending but have been withdrawn from consideration as being directed to a non-elected species. Presumably, these claims would be rejoined upon the allowance of generic claims 1 and 15.

Applicants have added a paragraph to the specification at page 5. Specifically, applicants have added a description of the compounds disclosed in PCT Application No. PCT/US98/17830. No new matter has been added, because PCT Application No. PCT/US98/17830 was incorporated by reference into the present application (see, p. 5, second full paragraph).

Claims 1 and 15 have also been amended to recite that radical Y from the group of compounds excluded from the claimed invention can be  $\text{-NH}_2$  and not  $\text{-NH}$ . These amendments are supported in two ways. First, it is apparent, and would be apparent to one of skill in the art, that the Y radical cannot be  $\text{-NH}$ , as that would not fill all of the available valences on the nitrogen, and that  $\text{-NH}_2$  must have been what was intended. Second, and perhaps more importantly, WO 99/10321 – which is the publication of PCT application PCT/US98/17830 – is incorporated by reference into the present application. (See specification, p. 5, second full paragraph). That application clearly discloses the compounds excluded by the presently claimed invention, including the fact that Y can be  $\text{-NH}_2$  (see, e.g. Abstract). No new matter has been added.

### **Formal Objections**

The Examiner has requested a substitute Abstract which did not include the word “comprising.” Applicants have provided such a substitute Abstract. The Examiner has also objected to a misspelling of the word “compound” in claim 15. This error has been corrected. Applicants, therefore, believe that all formal objections have been appropriately addressed and obviated.

### **Written Description Rejection under 35 U.S.C. § 112, first paragraph**

The Examiner has rejected claims 1-5, 12, 14-19 and 26 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. According to the Examiner, applicants were

“not in possession of the broad genus “a compound” that is able to decrease ATP levels in the microbe by at least 10% and not kill mammalian cells after 24 hours in vitro (claim 1) or “a compound” that produces overexpression of the b-subunit of ATP synthase (claim 15)...[nor] of the broad genus of “a microbially-based infection.”

(Office Action, pp. 2-3). Applicants respectfully traverse.

As is undoubtedly well known to the Examiner, “there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed.” MPEP 2163, citing *Wertheim*, 541 F.2d at 262. In this instance, of course, both claims 1 and 15 are original claims and therefore are presumptively described. The MPEP also makes clear that “the examiner should evaluate each claim to determine if sufficient structures, acts, or functions are recited to make clear the scope and meaning of the claim, including the weight to be given the preamble.” MPEP 2163. Again, in this case, the language of the claims is crystal clear in

describing what compounds meet the requirements of the claimed method. For example, claim 1 explicitly provides details on how to measure the ability of a compound to decrease ATP in a microbe.

Furthermore, it must be emphasized that applicants are not claiming compounds which are characterized by particular functionality. Instead, what applicants have invented is a new method of treating microbially-based infections, which comprises the administration of compounds which decrease ATP levels in the microbes. Applicants submit that the Examiner's reliance on the statement in the MPEP that "if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is 'not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence'" is misplaced. As noted above, applicants are not claiming compounds which decrease ATP levels in microbes. Instead, applicants have found that decreasing ATP levels in infection-causing microbes can treat such infections. This is quite clearly "described" in the specification within the meaning of § 112, notwithstanding the large number of compounds which might be used in the claimed methods.

Moreover, with respect to claims 5, 14, 19, and new claim 28, these claims explicitly set forth the compounds and/or microbially-based infections, and even under the Examiner's theories are described in the specification.

In view of the foregoing, applicants submit that the claims are in compliance with the written description requirement, and request reconsideration and withdrawal of this rejection.

### **Rejections under 35 U.S.C. § 102**

The Examiner has rejected claims 1-3 and 14-17 under 35 U.S.C. § 102(b) as allegedly being anticipated by Townsend, et al., WO 99/10321 ("Townsend"). The rejection appears to have hinged on the contention that compound SI-73 as disclosed at page 20 of Townsend was not excluded from the scope of the claimed method. However, as described in detail above, compound SI-73 is in fact, excluded from the presently pending claims. Therefore, Townsend cannot anticipate the presently claimed invention and the anticipation should be withdrawn.

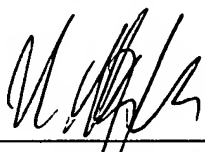
The Examiner has also rejected claims 1-5, 12, 14-19 and 26 under 35 U.S.C. § 102(e) as allegedly being anticipated by Kuhajda, et al., US 21006/0247302 ("Kuhajda"). Applicants traverse. Kuhajda discloses a number of different compounds and classes of compounds, including one which appears in the present application as compound VII and which is the presently elected species. Kuhajda also discloses that some of its compounds can have anti-microbial properties. However, compound VII (shown in Kuhajda as Compound 74) was not tested for anti-microbial properties (see, p. 35 which shows the results of biological testing of compound 74). Accordingly, applicants submit that Kuhajda does not disclose a method which contains each and every element of the claimed method, either explicitly or inherently. Accordingly, applicants request withdrawal of this rejection.

**Conclusion**

In view of the foregoing, applicants submit that the claims are in condition for allowance, and earnestly solicit prompt notice to that effect. However, the Examiner is respectfully requested to telephone the undersigned if it is believed that an telephone call could advance prosecution.

Respectfully submitted,

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